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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/117, 357      09/22/98      STOCKEMANN

K      SCH1655

EXAMINER

HM12/1113      DELACROIX MUIRHEI, C

ART UNIT	PAPER NUMBER
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1614      14

DATE MAILED:

11/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/117,357</b>	Applicant(s)
	Examiner <b>Cybille Delacroix-Muirheid</b>	Group Art Unit <b>1614</b>
<b>STOCKMANN et al.</b>		

Responsive to communication(s) filed on Aug. 28, 2000.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 11-16, 20-22, 30, and 33-36 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 11-16, 20-22, 30, and 33-36 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### **DETAILED ACTION**

The following is responsive to Applicant's amendment received Aug. 28, 2000.

Claims 10, 17-19, 23-29, 31, 32, 37-39 are cancelled. No new claims are added. Claims 11-16, 20-22, 30, 33-36 are currently pending.

In view of newly discovered prior art, the finality of the office action mailed May 26, 2000 is **withdrawn**. Prosecution on the merits is reopened.

#### *Claim Objections*

1. Claim 30 is objected to because of the following informalities: claim 30, depends upon cancelled claim 17. Appropriate correction is required.

PLEASE NOTE: the amendment to claim 30, line 1, was not entered because claim 30 is already dependent upon claim 17 and not claim 34. Further clarification is requested.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 34-36, 11-16, 20-22, 30, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goulding et al.

Goulding et al. disclose a method for studying the effects of the anti-estrogen, Tamoxifen, on bone loss in rats treated with buserelin, an LHRH agonist. Specifically, Goulding et al. studied such effects by treating rats with 25 µg/kg body weight of buserelin and 20 mg/kg body weight of Tamoxifen (Group D) and monitoring the bone resorption. Results prove that Tamoxifen slowed bone loss and bone-thinning effects of buserelin in the rats. In view of the results, Goulding et al. suggest that the bone protecting effects of Tamoxifen should be studied in women undergoing LHRH agonist therapy. Please refer to the abstract; page 147, Fig. 2; page 148, Discussion, first full paragraph.

Goulding et al. do not specifically disclose a method of administering buserelin and Tamoxifen to a human patient; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Goulding to include human patients, especially women, because the desirable results provided by the Goulding et al. study prove that Tamoxifen is successful in inhibiting the inherent bone-thinning effects of buserelin in rats. Such a modification would have been motivated by the reasoned expectation of preventing the bone-thinning effects of buserelin which are also observed in human patients, particularly women. Moreover, Goulding et al. teaches that Tamoxifen is known to slow bone loss in post-menopausal women because it acts as an estrogen agonist in the skeleton. Please see the abstract; page 148, Discussion, last four lines to page 149 line 2.

Concerning claims 12, 15, 16, 21 and 35, which claim administration of anti-estrogens (Raloxifene, Droloxifene and Centchroman) other than Tamoxifen, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Tamoxifen with these other anti-estrogens because, absent evidence to the contrary, one of skill in the art would reasonably expect the claimed anti-estrogens to have similar properties as Tamoxifen.

In addressing claims 13, 20, 30 and 33, modification of the method in Goulding et al. to administer buserelin orally as well as the use of LHRH antagonists or peptidergic LHRH analogues in the method of Goulding would have been obvious and well within the capability of the skilled artisan. Finally, since Goulding et al. establish that the effect of Tamoxifen is dose dependent, it would have been obvious to one of ordinary skill in the art at the time the invention

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was made to further modify the dose of Tamoxifen in the Goulding et al. study so as to optimize its inhibiting effect against buserelin.

*Conclusion*

Claims 11-16, 20-22, 30, 33-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM  
Nov. 7, 2000

Dwayne C. Jones  
PRIMARY EXAMINER